

REMARKS

Status Summary

Currently, claims 1-26 are pending. Claims 1-26 presently stand rejected. Upon entry of this amendment, claims 1 and 6 will be amended. Reconsideration of the application and entry of the Amendment is respectfully requested for at least the reasons set forth below.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-4, 6-16, 18-22, and 25-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender (hereinafter, "Ender").

Recitation of the Independent Claims Rejected under 35 U.S.C. § 102(b)

Independent claim 1 recites a longitudinally extending intrafocal plate for securing bone fractures. The intrafocal plate includes an elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, a leading end, and a trailing end and sized to overlay a fracture site. The elongated intrafocal plate has a longitudinally extending intrafocal resilient body element secured with the intrafocal plate element adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is secured to the surface of the plate element. Also, the resilient body element is secured with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is secured to the surface of the plate element and the trailing end of that surface. The overhanging heel extends

downwardly below the location at which the resilient body element is secured to the surface of the plate element. The heel serves to help stabilize the fracture site. The body element is formed to extend generally in the lengthwise direction of the surface and wherein the other end of the body element defines a pin element.

Independent claim 6 recites a longitudinally extending intrafocal plate for securing metaphyseal bone fractures. The intrafocal plate includes an elongated intrafocal plate element having a surface at one end thereof with one or more apertures therein in defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element affixed to and depending from the trailing end of the surface so that the body element forms an acute angle with the surface and extends generally in a lengthwise direction of the surface. The body element is adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is affixed to the surface of the plate element. Also, the resilient body element is affixed with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is affixed to the surface and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is affixed to the surface of the plate element. The heel serves to help stabilize the fracture site. The body element defines a shoulder at one end at the juncture of the body element and the surface with a pin at the other end of the body element.

Independent claim 7 recites a longitudinally extending intrafocal plate for securing bone fractures. The intrafocal plate includes a plate element having a leading end and a trailing end, wherein the trailing end comprises an overhanging heel sized to overlay a fracture site, wherein the overhanging heel stabilizes the fracture site. The intrafocal plate further includes a longitudinally extending resilient body element having a first end and a second end, wherein the first end of the body element is connected to the plate element at a location between the leading end and the trailing end.

Independent claim 15 recites a longitudinally extending intrafocal plate for securing metaphyseal bone fractures. The intrafocal plate includes an elongated plate element having at least one aperture and defining a leading end and a trailing end with the trailing end sized to overlay a fracture site. The intrafocal plate also includes a longitudinally extending body element connected to the elongated plate. The intrafocal plate further includes an overhanging heel formed between the location at which the body element is connected to the elongated plate element and the trailing end of the elongated plate element, wherein the overhanging heel prevents over reduction of the fracture site.

Independent claim 21 recites an intrafocal plate for stabilizing a fracture site. The intrafocal plate includes a plate element having a first end and a second end. The intrafocal plate also includes a body element having a sinuous shape and connected between the first end and the second end of the plate element. The second end of the plate element stabilizes the fracture site.

Applicant's Arguments Against the Rejections under 35 U.S.C. § 102(b)

Applicant respectfully submits that Ender does not anticipate independent claims 1, 6, 7, 15, and 21 or the claims that depend therefrom. In particular, Ender does not disclose all the features of claims 1, 6, 7, 15, and 21.

For example, claims 1, 6, 7, 15 and 21 all recite that the body and plate elements are secured, affixed, or connected together. Ender does not disclose, suggest or teach an intrafocal plate including a body element secured/affixed/connected to a plate element. The bone nails 4 disclosed in Ender are separate from the insert member 5 and are introduced into the medullary canal through an insert member 5. (See Ender, col. 4, line 65 through col. 5, line 1.) The insert member includes a flange 7 for preventing the insert member from entering the medullary canal at too great a distance. (See Ender, col. 5, lines 1-4.) Thus, it is clear that the bone nails and the insert members are separate.

Ender acknowledges and expresses concern that the bone nails are likely to slide back out from the insert member, and thus need to be affixed within the medullary canal of the bone since they are separate components. Thus, reinforcing that the bone nails and the insert members are separate. Ender states that "for reliably preventing the distal ends of the nails from subsequently projecting outwardly from the insert member 5, it is convenient to close this insert member. This can, for example, be effected by pouring hardening material...into the insert member. This material, after having become hardened, fixes the distal nail ends in a non-displaceable manner." (See Ender, col. 5, lines 59-66.) Even after the material hardens, the material must be fixed within the guiding channel. Alternatively, the guiding channel can be closed by positioning a lid 18

to the insert. "The guiding channel 6 can, however, also simply be closed by a lid 18 as is indicated in Figures 3 and 4." (See Ender, col. 6, lines 3-4.) The lid can be affixed to the insert by mating inner and outer threads, inserting pins of the lid to recesses within the insert, or by press fitting the lid to the insert. (See Ender, col. 6, lines 5-14.)

By contrast, claims 1, 6, 7, 15 and 21 recite that the body and plate elements are secured, affixed, or connected together. As stated in the specification, "Further, applicant contemplates that body element 30B depending outwardly and downwardly from plate element 30A...may be formed as an integral part and extension of plate element 30A." (See the present application, page 4, paragraph 40, and Figures 7A-9B.)

Furthermore, as pointed out in the Response dated October 29, 2008, claim 21 further recites that the body element of the intrafocal plate has a sinuous shape. The Examiner mentions that Ender discloses a sinuous shape in the Office Action dated January 22, 2009, but does not point out where it discloses this. As previously stated, the term "sinuous" refers to an element having a wavy form, windy, multiple curves, bends, or turns. (See Exhibit A, definitions of "sinuous" from [www.meriam-webster.com](http://www.meriam-webster.com) and [www.dictionary.com](http://www.dictionary.com).) However, Ender discloses bone nails that are formed of an elastic material that curve in a single direction as they are being guided through the guide channel into the medullary canal. (See Ender, col. 4, lines 46-50, and Figure 1.) There is no mention in the specification of Ender that the bone nails are formed as, or are capable of forming, a sinuous shape.

For at least the reasons set forth above, Ender does not anticipate claims 1, 6, 7, 15 and 21. Since claims 2-4 depend from claim 1, claims 8-14 depend from claim 7, claims 16, 18-20 depend from claim 15 and claims 22 and 25-26 depend from claim 21,

applicant respectfully submits that these claims are also not anticipated by Ender. Applicant, therefore, respectfully requests that the rejections of claims 1-4, 6-16, 18-22, and 25-26 under 35 U.S.C. § 102(b) be withdrawn and the claims allowed at this time.

#### Claim Rejections – 35 U.S.C. § 103

Claims 5 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ender in view of U.S. Patent No. 4,483,335 to Tornier (hereinafter, "Tornier"). Claims 23-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ender in view of U.S. Patent No. 5,013,314 to Firica et al. (hereinafter, "Firica"). These rejections are respectfully traversed.

#### Arguments Against the Rejections under 35 U.S.C. § 103

Neither Tornier nor Firica overcome the shortcomings of Ender. Claim 17 depends from claim 15 described above. Claims 22-23 depend from claim 21 described above. Claim 5 recites an intrafocal plate for securing bone fractures. The intrafocal plate includes an elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element integral to the surface adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is integral to the surface of the plate element. Also, the resilient body element is integral with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to

the surface of the plate element and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is integral to the surface of the plate element. The heel serves to help stabilize the fracture site. The other end of the body element defines a pin with the intrafocal plate including one or more screws for insertion through one or more apertures defined in surface of the plate element.

Regarding claims 5 and 17, there is no motivation to combine Ender and Tornier in the manner suggested by the Examiner. As stated above, Ender does not disclose the intrafocal plate having a longitudinally extending intrafocal resilient body element integral or connected to the plate element. Further, to change Ender in such as manner would destroy its principles of operations.

Both claim 5 and claim 17 recite an intrafocal plate that includes a plate element, a body element and a screw. Ender is secured to a bone by one of three methods: (1) by mating inner and outer threads of a lid and an insert, (2) inserting pins of the lid to recesses within the insert, or (3) by press fitting the lid to the insert. (Col. 6, lines 5-14). The device of Ender is designed such that after the bone nails are adhered within the bone, the lid is interference fit to the insert. Therefore, Ender already teaches a method of securing the device to the bone. There would be no reason or motivation to combine the apertures and screws in the plate element of Tornier with the insert/lid structure of Ender.

Further, it is likely that the addition of an aperture/screw configuration as disclosed in Tornier would interfere with the insert and bone nails of Ender. It is well settled that a combination which abandons or destroys the intended functionality of the

primary reference fails to establish a *prima facie* case of obviousness. One of ordinary skill in the art would not be motivated to make a modification that significantly alters the design of the primary reference in the absence of express or explicate teaching. In short, there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Applicant submits that the proposed combination of the aperture/screw configuration of intrafocal plate disclosed in Tornier with the teaching of a lid/insert structure disclosed in Ender is not proper because the intended function of the lid/insert structure disclosed in Ender would be destroyed. In particular, the alternate arrangement disclosed in Tornier would likely interfere with the bone nails and insert of Ender. In order to secure a screw through an aperture of the lid of Ender, the screw would most likely abut or engage the insert and bone nails of Ender, possibly displacing the bone nails.

If the proposed modification changes the principle of operation of the prior art reference, then the reference is not sufficient to render the claims *prima facie* obvious. M.P.E.P. 2143.01. In re Ratti, 270 F.2d 810 (CCPA 1959). Applicant thus submits that the proposed combination of Ender's device with Tornier's alternate arrangement would change the operating principle of the lid/insert of Ender. In particular, maintenance of the lid and bone nails within a bone through an interference fit, or a fit without the use of further drilling into the bone, between would be lost.

Regarding claims 23-24, applicant reiterates that Firica does not disclose, teach, or suggest a body element having a first portion that curves away from the plate element and second and third portions that curve toward the plate element, as recited



by claim 23. As shown in Figures 66-70, Firica discloses a plate system having a body element that only has one portion that curves towards the plate element. Again, there is no disclosure in the specification of Firica of a rod that bends in more than two directions relative to the end anchored to the bone such that one portion extends away from the bone and two portions extend toward the bone. Even assuming arguendo that the arrows pointing to the image from Firica in the Official Action dated January 22, 2009, showed three curved portions. at best, they dubiously illustrate a first portion extending away from the plate, a second portion extending toward the plate and a third portion extending toward the plate.

Further, as illustrated by the Examiner, the first and third portions, as defined by the Examiner, extend in the same direction instead of the second and third portions that extend in the same direction as recited by claim 23. Such a curved body element as recited by claim 23 and supported by the specification is not disclosed, taught or suggested by Ender or Firica. Therefore, claims 23 and 24 are not rendered obvious by the Ender and/or Firica.

For the reasons set forth above, claims 5, 17, and 23-24 are not rendered obvious by the cited references. Accordingly, applicant respectfully submits that the rejections of claims 5, 17, and 23-24 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that claims 1-6 of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

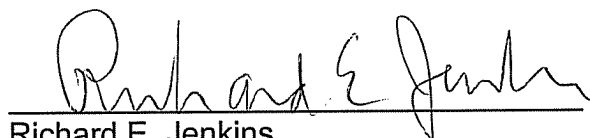
The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR, & HUNT, P.A.

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